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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,418	08/23/2001	Avi Ashkenazi	P5009R1	2589

7590 06/21/2005

Attn: Mark T. Kresnak, Ph.D.
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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,418	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.

DETAILED ACTION

Claims 1-13 and 15 are pending and under consideration.

The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants amendments.

The rejection of claims 1-6, and 11-13 under 35 U.S.C. 112, first paragraph (deposit requirement) is withdrawn in view of applicants amendments.

The rejection of claims 1-8 and 12-15 under 35 U.S.C. 102(b) as being anticipated by WO99/46281 (Wood et al., cited by applicants) and the rejection of claims 1-9 and 21-15 under 35 U.S.C. 102(b) as being anticipated by WO00/37638 (Ashkenazi et al., cited by applicants) is withdrawn in view of applicants arguments regarding priority.

Information Disclosure Statement

The information disclosure statement filed 3/4/2005 has been considered. References 37 and 38 indicate that applicants are aware of various sequences that have identity to the protein to which the claimed antibodies bind. However, as "Blast results" are not publications, the references, although considered, will not be printed on the face of the patent. If applicant wishes to have individual results printed on the face of the patent, they should have been listed individually on the PTO-1449.

Specification

The objections to the specification and new matter objection are withdrawn in view of applicants arguments.

Priority

It is noted that the protein to which the claimed antibodies bind, identified herein as TAT171, but in other applications as PRO866, was shown to induce mouse kidney mesangial cell proliferation and to induce the switch from adult to fetal hemoglobin in PCT US00/04341, which published as

WO 00/53756, filed 2/18/00. In view of applicants arguments pertaining to the incorporation by reference, priority is set at 2/18/00. Applicants further argue that PCT/US99/05028 (WO99/46281), discloses the use of PRO866 as "an anti-proliferative agent" at page 275, lines 1-23. The Examiner has looked at pages 268-281 (of the 566 pages) of WO 1999/046281, the publication of PCT/US99/05028, and no information relevant to PRO866 is found therein. Accordingly, priority to that application is *denied.* Should applicants wish to continue arguing priority to this or any other document, they are requested to *provide* the relevant pages of the documents with their arguments.

In view of the above, priority for this application is set at 2/18/2000.

Rejections over Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12-13 and 15 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,682,902 (Harkins et al.) for reasons cited in the previous Office Action. The Harkins patent merits priority to the filing date of application 60/172,370, filed 12/16/1999. Applicants arguments regarding priority date are not persuasive for reasons cited above. Applicants further argue at page 8 of the response filed 3/14/05 that Harkin do not disclose antibodies within the metes and bounds of the claims. This argument has been fully considered but is not deemed persuasive because Harkins discloses and claims methods that use antibodies

to a protein that is identical to SEQ ID NO: 8 of this application at all but 3 amino acids, at positions 38, 122 and 242, as well as antibodies to specific fragments that are identical to the corresponding portions of SEQ ID NO: 8; see claims 1 and 4-7. Applicants have provided no argument, fact, evidence, or scientific evidence to support their argument that the antibodies of Harkins would not meet the metes and bounds of the claims.

Claims 1-9, 12-13 and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO98/45442 (Sheppard et al., cited by applicants) for reasons cited in the previous Office Action. Applicants arguments regarding priority date are not persuasive for reasons cited above.

Claims 1-8, 12-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,871,969 (Hastings et al., cited by applicants). The Hastings patent merits priority to at least 2/12/1997. This rejection is maintained for reasons of record.

Applicants argue at page 8 of the response filed 3/14/05 that Hastings et al. do not disclose antibodies within the metes and bounds of the claims. This argument has been fully considered but is not deemed persuasive because Hastings discloses a protein designated human neuronal attachment factor-1 (NAF-1), which is 98.9% identical to SEQ ID NO: 8. Monoclonal and polyclonal antibodies are included, as well as labeled antibodies, at col. 24-26. Applicants have provided no argument, fact, evidence, or scientific evidence to support their argument that the antibodies of Harkins would not meet the metes and bounds of the claims.

Claims 1-8, 12-13 and 15 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,287,777 (Sytkowski et al., cited by applicants). The Sytkowski patent merits priority to at least 8/10/1999.

Applicants argue at page 8 of the response filed 3/14/05 that Sytkowski et al. do not disclose antibodies within the metes and bounds of the claims. This argument has been fully considered but is not deemed persuasive because Sytkowski discloses gene designated NPG-1, that is differentially expressed in prostate tumors (title). The encoded protein is 88.9% identical

to SEQ ID NO: 8, and is 100% identical at residues 1-144. Monoclonal and polyclonal antibodies are included, as well as labeled antibodies, at col. 26-29. Applicants have provided no argument, fact, evidence, or scientific evidence to support their argument that the antibodies of Sytkowski would not meet the metes and bounds of the claims.

Claims 1-8, 12-13 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by WO99/46281 (Wood et al., cited by applicants) .

Wood et al. teaches a polypeptide that is 100% identical to SEQ ID NO:8. Antibodies to the protein are taught for example at pages 135-137, including monoclonal, polyclonal and humanized, which are found at page 196. Though Wood does not specifically disclose production of antibodies in bacteria or CHO cells, the limitations of claims 12 and 13 do not affect the nature of the antibodies so produced, which are therefore anticipated by those of Wood. Coupling of antibodies to detectable markers is disclosed at page 198. As the detectable markers include radioactive isotopes, the limitations of claims 6-8 are inherently met. Applicants arguments pertaining to priority date are not persuasive for reasons cited above. The inventive entity of Wood et al. differs from that of the instant application. Hence, the reference is available under 35 U.S.C. §102(a).

Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Higashijima et al., Developmental Biology 192:211-227, 1997. Higashijima et al. disclose production of polyclonal antibodies using a peptide corresponding to residues 188-202 of SEQ ID NO: 8 of this application. Accordingly, the claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Harkins or Sheppard, either one in view of U.S. Patent Number 5,208,020 (Chari et al.).

Claims 10 and 11 contain the limitation that the toxin to which the claimed antibody is conjugated is a maytansinoid, or calicheamicin. Each of the primary references teach the claimed antibodies conjugated to a toxin, but do not specifically teach either of these two toxins.

Chari et al. disclose and claim a cytotoxic agent comprising one or more linked to a monoclonal antibody (see, e.g. claim 1). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute maytansinoids as the toxin in the antibody/toxin conjugates of any of the primary references for their known and expected properties, as taught by Chari et al. Accordingly, the invention, taken as a whole, is *prima facie* obvious.

Applicants arguments regarding priority date are not persuasive for reasons cited above.

Claims 3-9, 12-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al., Developmental Biology 192:211-227, 1997 in view of Lal et al., U.S. Patent No. 5,932,445.

Lal is cited as evidence that production of monoclonal, chimeric, and isotope-labeled antibodies was notoriously old and routine in the art at the time the invention was made. Monoclonal and polyclonal antibodies are disclosed at the paragraph bridging columns 20-21. Further discussion of antibodies, including monoclonal, polyclonal and single chain and humanized antibodies, as well as radioactively labeled antibodies, is found at column 24-25.

Accordingly, the invention as claimed is anticipated by Lal et al. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the antibodies of Higashijima by making monoclonal, fragment, chimeric, radioactive and labeled antibodies as taught by Lal et al. as being routine in the art at the time the invention was made, to attain the known and art-recognized advantages of such, as taught by Lal et al. . One would have been motivated to do so to obtain homogeneous and useful reagents for the immunohistology performed by Higashijima et al. Accordingly, the claims, taken as a whole, are *prima facie* obvious over Higashijima et al., in view of the state of the art as evidenced by Lal et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner

6/20/05